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(54) Title: MIXTURES OR COMPLEXES CONTAINING CALCIUM AND SULFATE

(57) Abstract

Inorganic compositions comprising a mixture and/or complex of calcium-containing and sulfate-containing materials are disclosed for treating a variety of diseases, injuries and conditions, including wound healing, pain, itch, inflammation, abnormal cell proliferation, or infections caused by fungal, bacterial, rickettsial or viral agents, and similar conditions. The inorganic compositions are derivable from peat or peat-related substances, and may alternatively be synthetically produced.

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MIXTURES OR COMPLEXES CONTAINING CALCIUM AND SULFATE

Technical Field

The present invention relates generally to novel compositions and methods suitable for treatment of disease, injury and other disorders. More specifically, the invention relates to inorganic calcium-containing and sulfate-containing compositions, methods of isolation, methods of synthesis, and pharmaceutical compositions suitable for accelerating wound healing, providing relief of pain, itch or inflammation, reducing abnormal proliferative cell growth, or providing anti-fungal, anti-viral, or anti-bacterial activity.

Background of the Invention

Clinical use of available treatments for diseases involving epidermal conditions is often limited by toxicity, either systemic or local. For example, methotrexate, while generally effective for treating epidermal conditions when administered orally, is rarely administered orally for fear of hepatic or bone marrow toxicity. Topical application of methotrexate has been deemed ineffective. Similarly, although topical application of 5-fluorouracil may be an effective treatment for psoriasis, it is generally considered to be unacceptably irritating. Steroid therapy, while effective, has so many side effects that prolonged use is discouraged. Photochemotherapy with psoralens and ultraviolet light, or PUVA (psoralens and UV treatment), is generally effective for treatment of epidermal conditions,

but it is inconvenient and causes acute side effects, as well as having photomutagenic and photocarcinogenic potentials.

Many of the existing treatments for wound healing and the relief of pain, itch and inflammatory conditions are only moderately effective. Moreover, their clinical use is often limited by toxicity or undesirable side effects. Considerable research effort has been devoted to elucidating the mechanisms involved with such conditions, but few satisfactory treatments have been developed. Likewise, most therapies available for treating neoplasms and abnormal proliferative cell growth produce undesirable side effects. The compositions of the present invention are therefore directed to pharmaceutical preparations and methods for treating a variety of disorders.

Summary of the Invention

In one aspect, the present invention provides novel calcium-containing and sulfate-containing compositions, and analogs and derivatives thereof, that function medicinally, therapeutically or pharmaceutically in the treatment of various diseases, injuries and conditions. Several mixtures and complexes of calcium-containing and sulfate-containing compositions of the present invention have demonstrated significant therapeutic benefit. A first class of inorganic compositions comprises mixtures of a calcium-containing component and a sulfate-containing component. Mixtures of calcium sulfate and potassium sulfate are especially preferred.

A second class of inorganic compositions includes complexes of a calcium-containing or potassium-containing component and a sulfate-containing component. Syngenite and apthitalite are especially preferred complexes and may be administered as a mixture with one or more of the above-mentioned calcium-containing or sulfate-containing components. A mixture of syngenite and calcium sulfate, for

example, is especially preferred therapeutic composition of the present invention. The compositions of the present invention may also comprise one or more of the following elements, which may be present in elemental form, ionic form, as a salt or chelate, or in any other form: sodium; magnesium; silicon; sulfur; chlorine; potassium; strontium; zinc; copper; nickel; and manganese.

The inorganic compositions of the present invention can be isolated from natural materials, such as peat, using the extraction and purification procedures disclosed herein. The inorganic compositions may alternatively be produced by combining and/or synthesizing the constituent components. Novel methods for synthesizing high purity syngenite are also disclosed herein.

The inorganic compositions of the present invention have produced therapeutic results in a variety of medicinal, pharmaceutical, and therapeutic applications in warm-blooded animals. Those applications may be characterized generally as promoting wound healing, treatment of pain, inflammation, itch, and inhibition of abnormal proliferative cell growth. Additionally, the inorganic compositions have demonstrated anti-fungal, anti-bacterial, anti-rickettsial and anti-viral properties and may also be used in cosmetic preparations.

Various delivery systems may be appropriate for administering the compositions of the present invention, depending upon condition and preferred treatment regimen. Topical delivery systems are effective and are generally preferred for most applications of the pharmaceutical composition of the present invention. Topical formulations may be produced by dissolving or combining the inorganic compositions of the present invention in an aqueous or nonaqueous carrier. Suitable carriers are well known and are described below.

Brief Description of the Drawings

Figure 1 shows an elution profile of a 0.5-30Kd fraction from a peat extract purified by High Performance Liquid Chromatography (HPLC) according to the methods described herein.

Figure 2 illustrates the X-ray powder diffraction analysis of standard gypsum published by the Joint Committee on Powder Diffraction Standards ("JCPDS") Library.

Figure 3 illustrates the X-ray powder diffraction analysis for syngenite published by the JCPDS Library.

Figure 4 shows an x-ray powder diffraction analysis spectrum identifying gypsum ($CaSO_4 \cdot 2H_2O$) in a peat extract sample using X-ray powder diffraction analysis.

Figure 5 shows a spectrum identifying gypsum ($CaSO_4 \cdot 2H_2O$) and syngenite ($CaSO_4 \cdot K_2SO_4 \cdot H_2O$) in a peat extract sample using X-ray powder diffraction analysis.

Figure 6 depicts a spectrum identifying syngenite ($CaSO_4 \cdot K_2SO_4 \cdot H_2O$) and apthitalite ($K_3Na(SO_4)_2$) in a peat extract sample using X-ray powder diffraction analysis.

Figure 7 illustrates an X-ray powder diffraction analysis spectrum for syngenite produced synthetically according to the methods described herein.

Detailed Description of the Invention

The compositions of the present invention comprise a mixture and/or complex of a calcium-containing or potassium-containing component and one or more sulfate-containing components in a pharmaceutically acceptable formulation that is effective in the treatment of various diseases, injuries, symptoms or other disorders. All references to "components" in this application, in whatever form, are understood to include associated, dissociated, ionic, neutral, elemental, salt, hydrated, and other forms of the constituents. Thus, for example, a calcium sulfate component may be present in an associated form as a neutral or ionic species; as part of a larger complex; or in a

dissociated form in which calcium and sulfate are present as distinct, non-complexed neutral or ionic species. The term "composition" also contemplates mixtures of associated, dissociated and complexed constituents.

The term "mixture," as used herein, connotes a composition wherein the constituent components are present in their associated, dissociated, elemental, ionic, salt, hydrated and other forms. Thus, for example, a composition comprising a mixture of calcium sulfate and another sulfate-containing component, such as potassium sulfate, may comprise calcium sulfate and potassium sulfate typically not physically bonded to one another but rather in neutral or ionic forms and/or partially, substantially or completely dissociated into their respective species. A "mixture" of two components may be substantially or entirely dissociated. It is anticipated that the precise form(s) of the individual components in a mixture will vary depending, for example, upon the relative quantity of each component, the use of aqueous or non-aqueous carriers, and the desired pharmaceutical applications or methods of treatment.

The term "complex," as used herein, connotes a composition wherein individual constituents are associated, i.e., bound to one another covalently or non-covalently as a result of hydrogen bonding or other intra-molecular forces. Complexes may be present in neutral, ionic, salt, hydrated or other forms.

All references to "calcium sulfate" herein are understood to comprehend calcium sulfate in a non-hydrated form ($CaSO_4$), as well as in hydrated forms, e.g., $CaSO_4 \cdot \frac{1}{2}H_2O$ and $CaSO_4 \cdot 2H_2O$ (commonly referred to as gypsum), unless a composition, such as gypsum, is referred to specifically.

Suitable mixtures of a calcium-containing component and one or more sulfate-containing components include, for example, mixtures of calcium sulfate with another sulfate-containing component having a constituent chosen from one or

more of the following: magnesium, potassium, aluminum, sodium, silicon, sulfur, chlorine, calcium, silicon, strontium, zinc, copper, nickel or manganese. Calcium sulfate is a preferred calcium-containing component. Preferred sulfate-containing components include: $MgSO_4$, K_2SO_4, $Al_2(SO_4)_3$, $2CaSO_4 \cdot MgSO_4 \cdot K_2SO_4 \cdot 2H_2O$, $CaSO_4 \cdot K_2SO_4 \cdot H_2O$, $3CaO \cdot Al_2O_3 \cdot CaSO_4 \cdot 32H_2O$, $CaSO_4 \cdot Na_2SO_4$, $Na_2SO_4 \cdot 10H_2O$ and $K_2SO_4 \cdot 5CaSO_4$. Mixtures of calcium sulfate with potassium sulfate and/or syngenite ($CaSO_4 \cdot K_2SO_4 \cdot H_2O$) are especially preferred. $K_3Na(SO_4)_2$, $NaAlSi_3O_8$, and/or $KAlSi_3O_8$ may also be incorporated in the mixtures. The mixtures are combined in a carrier, as described below, and administered for treatment.

Therapeutically important compositions of the present invention may also comprise a complex of a calcium-containing or potassium-containing components with one or more sulfate-containing components. Syngenite ($CaSO_4 \cdot K_2SO_4 \cdot H_2O$) is a preferred complex. Other complexes, such as $K_3Na(SO_4)_2$ may also be used. According to especially preferred embodiments, a complex of calcium sulfate with one or more other sulfate-containing components, such as syngenite, is administered in a carrier, in the form of a mixture with another sulfate-containing component. The mixture of syngenite and calcium sulfate is an especially preferred composition. Mixtures of syngenite with other sulfates, such as $MgSO_4$, K_2SO_4, $Al_2(SO_4)_3$; $2CaSO_4 \cdot MgSO_4 \cdot K_2SO_4 \cdot 2H_2O$, $3CaO \cdot Al_2O_3 \cdot CaSO_4 \cdot 32H_2O$, $CaSO_4 \cdot Na_2SO_4$, $Na_2SO_4 \cdot 10H_2O$ and $K_2SO_4 \cdot 5CaSO_4$, may also be used. $K_3Na(SO_4)_2$, $NaAlSi_3O_8$ and/or $KAlSi_3O_8$ may also be incorporated in the mixtures.

The mixtures and complexes forming the compositions of the present invention may be derived from natural sources, such as peat, or they may be derived synthetically. The biologically active inorganic compositions of the present invention were initially discovered in peat extracts, and

considerable data relating to naturally derived peat materials has been collected.

According to one aspect of the present invention, the inorganic preparations comprise an alkaline, aqueous or organic, or mixture thereof, extract of peat prepared according to the methods disclosed herein. The term peat, as used herein, refers generally to microbial degradation products of biomass, including peat and peat-related substances such as minerals, coal and coal-derived materials, including leonardite and lignite, and humic and fulvic acid preparations.

Peat extracts are prepared by extracting peat with aqueous solutions, organic solutions or water-miscible organic solvents at temperatures from below room temperature up to the boiling point of the solvents, but preferably below the boiling point of the solvent. Extraction at room temperature is quite suitable; however, the speed of extraction and total amount of active composition isolated are generally enhanced by carrying out the extraction treatment at elevated temperatures. According to preferred embodiments, purified peat preparations are prepared from Bonaparte peat. Bonaparte peat is hypnum peat obtained from Bonaparte Meadows, a peat bog near Bonaparte Lake, Washington, U.S.A. More specifically, the bog is located approximately 25 miles east of Tonasket, Washington, U.S.A., in Secs. 17, 20 and 29, T. 38 N., R. 30E, in Eastern Okanogan County.

Basic, aqueous solvents, particularly those containing alkali metals, alkaline earth metals and ammonium hydroxides, carbonates and bicarbonates, are preferred for peat extraction. Other organic solvents, or a water-miscible organic solvent mixed with an aqueous solvent, may also be used. It is preferred to use extracting solvents having a pH of at least 9, preferably using potassium- and sodium-containing bases. Potassium hydroxide (KOH) is an especially

preferred base for peat extraction.

Biologically active factors contained in the peat preparation are separated or removed from the residual solids by customary methods such as filtration, ultrafiltration, centrifugation, and decantation.

Peat preparations are complex mixtures which contain inorganic and organic constituents that may have molecular masses as large as several hundred thousand daltons. Various fractions of purified peat preparations have been found to exhibit biological activity and are referred to herein according to their molecular mass or fraction or sample number. For example, 10-30Kd peat preparation refers to a peat preparation comprising constituents having a molecular mass between about 10,000 and 30,000 daltons. Various fractions isolated from peat differ in the profile of their biological activities. A peat extract identified as peak #11 (see Example 3) contains a high level of biological activity. Likewise, samples #44 and #46, described in Example 4, exhibit significant biological activity.

Biologically active constituents of fractionated peat preparations were identified as $CaSO_4 \cdot 2H_2O$ (gypsum), $CaSO_4 \cdot K_2SO_4 \cdot H_2O$ (syngenite) and $K_3Na(SO_4)_2$ (apthitalite) by X-ray powder diffraction analysis. Each biologically active composition was identified by comparison of an X-ray powder diffraction spectrum of a fractionated peat extract to a standard spectrum of the Joint Committee of Powder Diffraction Standards (JCPDS) Library. The standard and experimental X-ray power diffraction spectra are illustrated in Figs. 2-6.

The elemental constituents present in a peat extract were identified by qualitative analysis using high resolution X-ray fluorescence spectrometry (XRF). The following elemental constituents were identified: sodium; magnesium; silicon; chlorine; potassium; calcium; strontium;

zinc; copper; nickel; and manganese. It is believed that one or more of these elemental constituents contribute to the biological activity of peat preparations.

The preparations of the present invention have been described above specifically with respect to compositions derived from peat. The compositions of the present invention may also be derived from other sources. High purity calcium sulfate and hydrated forms of calcium sulfate, including $CaSO_4 \cdot 2H_2O$ (gypsum), $CaSO_4 \cdot \frac{1}{2}H_2O$, and the like, are commercially available from a variety of sources. Potassium sulfate (K_2SO_4) and many of the other sulfate-containing compositions described herein are likewise commercially available. Others of the inorganic complexes disclosed herein may not be commercially available but are available from natural sources. For example, $K_3Na(SO_4)_2$, also known as apthitalite, is not commercially available, but may be obtained as a naturally occurring mineral or from other natural sources, i.e., peat, or it may be produced in the lab according to the protocal of Yanat'eva, O.K., et al., Chem. Abstr. 91 (2): 7031y (1979). Components such as $2CaSO_4 \cdot MgSO_4 \cdot K_2SO_4 \cdot 2H_2O$, $3CaO \cdot Al_2O_3 \cdot 3CaSO_4 \cdot 32H_2O$, $CaSO_4 \cdot Na_2SO_4$, $Na_2SO_4 \cdot 10H_2O$, $NaAlSi_3O_8$ and $KAlSi_3O_8$ are not readily commercially available, but they may be obtained as naturally occurring minerals.

Syngenite ($CaSO_4 \cdot K_2SO_4 \cdot H_2O$), also referred to as the double salt of gypsum, is one of the preferred calcium- and sulfate-containing complexes, but it is not available commercially at high purity levels. Syngenite may be obtained as an occurring mineral or from other natural sources, such as mineral deposits or peat. Applicants are aware of the two following reported syntheses for syngenite: Calistru, C., et al., Chem. Abstr. 106(5):31984k (1986); and Yunusova, Z., et al., Chem. Abstr. 114(10):84755h (1990), but could not produce high purity syngenite according to the published methods. Applicants therefore developed the following novel protocol for synthetic production of

syngenite.

Syngenite can be synthesized, very expediently and economically, by mixing an aqueous solution of potassium sulfate with an aqueous solution of calcium sulfate. A molar excess of potassium sulfate is preferably provided to the reaction mixture. According to especially preferred embodiments, a molar access of potassium sulfate of about 3 fold to about 10 fold is provided in the reaction mixture. A detailed protocol for syngenite synthesis is provided in Example 6. That synthetic protocol yielded pure (>90%) syngenite.

The preferred method for administration of the compositions of the present invention will vary according to the type and location of the disease, injury or condition. Potentially useful methods of administration include topical application of preparation in an suitable aqueous or non-aqueous carrier, injection of the preparation in a carrier, and oral administration. The preparations may also be administered in a solid form, such as a powder or tablet. The novel compositions are preferably used topically, but may be used orally or parenterally, either individually or in a pharmaceutically acceptable composition further comprising a pharmaceutically acceptable, and preferably inert, carrier or diluent. The term "pharmaceutically acceptable carriers and diluents," as used herein, contemplates any carrier or other substance that is combined with the biologically active compositions for use in any one of the enumerated methods of administration.

Suitable aqueous and non-aqueous carriers are well known in the art. In general, any liquid, cream, gel or similar substance that does not appreciably react with the active ingredients and which is non-irritating is suitable. In a preferred embodiment mixtures and complexes of the present invention are administered in an aqueous carrier, but various non-aqueous solvents or emulsions may also be used

as carriers. Suitable carriers include, but are not limited to: 1,2,3,-trihydroxypropanol, triethanolamine, EDT, and the like. In addition, the preparations may also contain fragrances, colors, self-sterilizing agents, odor controllers and thickeners such as natural gums and/or stabilizers.

The biologically active constituents, e.g., syngenite and/or a calcium sulfate complex, are generally present in a pharmaceutic preparation in an amount of at least about 0.00001% to about 20%, typically about 0.001% to 2%, and preferably about 0.01% to 0.5% by weight. The concentrations of biologically active constituents such as syngenite and/or the calcium sulfate complex may be limited by their solubility in a given pharmaceutical carrier or diluent. In such a case, the limit of solubility can be the preferred solubility. However, higher percentages of biologically active constituents may be obtained by preparing a slurry, or other mixture wherein not all of the mixture or complex is in solution.

The inorganic compositions disclosed herein demonstrate therapeutic utility for a broad range of human and veterinary indications, including: promotion of wound healing; reduction of pain, itch and inflammation; inhibition of abnormal cell proliferation; and infections caused by fungal, bacterial, rickettsial or viral agents. More particularly, as described in the appended examples, the inorganic compositions disclosed herein have been found to be active for the treatment of skin disorders such as psoriasis and eczema, acne, seborrheic keratosis and actinic keratosis. They are very effective in treating dermatitis, burns and open wounds and provide pain relief from any number of conditions. The inorganic compositions are also useful in the prevention and treatment of herpes, conjunctivitis and athlete's foot, and may be efficacious in the treatment of AIDS.

Moreover, inorganic compositions of the present

invention effectively treat diseases which include multiple drug resistance, cystic fibrosis, cancers, asthma, rheumatoid arthritis and other inflammatory disorders. Cancers for which the inventive compositions are effective include squamous call carcinomas, epithelial carcinomas, bladder tumors and lung tumors. The compositions of the present invention are also suitable for use in cosmetic applications.

Administration of a therapeutically effective amount of the compositions is preferably begun at the first indication of pain or other disorder, and continued until symptoms disappear or cease to respond to treatment. A "therapeutically effective amount" means an amount effective to alleviate one or more symptoms, or reduce or ameliorate one or more causes of the disease, injury or disorder.

The following examples are presented for illustrative purposes only and should not be construed as limiting the invention in any way.

Example 1

Preparation of "Standard Extract" (SE)

Room temperature extraction process

One gram of peat recovered from Bonaparte Meadows was stirred for two hours at room temperature with 120 ml of 6 mM KOH. The mixture was centrifuged and the supernatant liquid was designated "Standard Extract" (SE). Alternatively, in a scaled up process, 1 kilogram of peat may be stirred with 12 liters of 6 mM KOH, followed by filtration to remove unwanted solids.

Elevated temperature extraction process

One gram of air dried peat was extracted by heating and stirring with 120 ml of 6 mM KOH for 20 minutes at boiling. The suspension was filtered and filtrate was referred to as "Standard Boiled Extract" (SBE). Alternatively, 1 kilogram of peat was stirred with 12 liters

of 6 mM KOH for 20 minutes at boiling, followed by centrifugation to remove the solids.

Example 2

Preparation of Purified Peat Compositions

The SBE or SE may be used "as is," but, a purified preparation is desirable for many purposes and was provided using ultrafiltration techniques. Potassium hydroxide (66.4 g) was added with stirring to 88 kilos of Bonaparte peat (approximately 53 kg dry-weight) suspended in 190 liters water. After 24 hours the solids were allowed to settle. The supernatant liquid was separated by decanting or filtering. This solution corresponds to SE. Upon lyophilization, this solution has been found to yield an average of 0.4 mg/ml solids. The SE was ultrafiltered through an Amicon polysulfone 30 Kd filter, which retained material of molecular mass greater than 30,000 daltons (>30Kd). The retained material (>30Kd) typically contained about 0.2 mg/ml solids. The filtrate, about 130 liters, contained materials of molecular mass <30Kd and contained an average of about 0.2 mg/ml solids. A 25 liter portion of this <30Kd solution was ultrafiltered through another Amicon filter which retained materials of molecular mass greater than 10Kd to give 250 ml of a retentate containing an average of 0.1 mg/ml solids.

Example 3

Preparation of Highly Purified Peat Composition

Peat was extracted, purified by ultrafiltration, and then further purified using HPLC. To prepare a standard extract, 65 kilograms of peat and 264 grams of KOH were stirred in 760 liters of water. After 24 hours the solids were allowed to settle. The supernatant liquid was filtered or decanted to produce the "Standard Extract." The standard extract was ultrafiltered through an Amicon hollow filter

cartridge 30Kd to yield a filtrate comprising 740 liters containing material of molecular mass <30Kd.

Although filtrates have been prepared using different size exclusion methods, all <30Kd fractions have been found enriched in materials having desirable biological properties. Peat preparations comprising the <30Kd fraction may be further resolved by processing on a .5Kd Amicon Spiral Wound Cartridge, which retains material having a molecular mass from .5-30Kd that is suitable for HPLC. The HPLC fraction was obtained by injecting a 250 ul portion of a .5-30Kd extract onto a Beckman 5 micron 10 mm x 25 cm C-18 (reversed-phase) High Pressure Liquid Chromatography column. A gradient of solvents beginning with Methanol (100%) and gradually changing to end with deionized water (100%) was passed through the column at a flow rate of 1.5 ml/min. The eluate was scanned by a UV detector set at a wave length 254 nm.

A fraction referred to as peak #11 contains a high concentration of biologically active material. Peak #11 eluted from 9 to 11 minutes in the HPLC system described above. Figure 1 illustrates the HPLC results and identifies peak #11. X-ray powder diffraction analysis identifies the significant compositions in peak #11 as gypsum [$CaSO_4 \cdot 2H_2O$] and syngenite [$CaSO_4 \cdot K_2SO_4 \cdot H_2O$]; and apthitalite [$K_3Na(SO_4)_2$]. Figures 2 and 3 illustrate the x-ray powder diffraction standard spectra for gypsum and syngenite, respectively, published by the JCPDS Library. Figures 4 and 5 illustrate spectra identifying gypsum (Figure 4) and both gypsum and syngenite (Figure 5) in the peat sample. Figure 6 illustrates a spectrum identifying both syngenite and apthitalite in a peak #11 peat sample.

Example 4

Alternate Peat Purification Preparation

An aqueous solution of peat was prepared and

allowed to stand unfiltered for a time period sufficient for a film to form on the surface, usually at least 1 week. The film was carefully skimmed from the surface and mixed with water. The resulting film solution was ultrafiltered through a 1Kd Amicon spiral wound cartridge to dryness and the >1Kd fraction was discarded. The solution <1Kd was then filtered through an Amicon spiral wound cartridge with a nominal <.5Kd exclusion. The retentate was lyophilized to dryness, reconstituted in water and called Sample #44. The filtrate of <.5Kd was concentrated by lyophilization and called Sample #46.

Samples #44 and #46 yield fractions with the same HPLC retention times as peak #11 from the SE, and similar proportion of calcium sulfate (gypsum) as the major aspect of their chemical compositions. Sample #46, when repurified by HPLC, eluted as a single peak that comprised two compounds, of which syngenite was the major component.

Example 5

Application of Peat Preparation to Human Patients

Numerous human trials were conducted to demonstrate the utility and effectiveness of treatments using the inorganic compositions of the present invention. The inorganic compositions administered to humans patients in the following studies were derived from natural peat sources unless otherwise indicated. The peat preparation administered to human patients was isolated from Bonaparte peat and purified as set forth in Example 2. Unless otherwise indicated, an aqueous 0.2% solution by weight of the 10-30Kd peat preparation ("Peat Preparation") was applied topically three times a day. Other peat fractions, including a 3-30Kd fraction of standard extract, peak #11 and/or samples #44 and #46 were applied topically two and occasionally three times daily in a liquid carrier in the trials indicated. Aqueous and emollient peat preparations

were administered.

Psoriasis Patients 1-5

Studies were carried out on human patients 1-5 having long-standing psoriasis and in whom conventional therapy gave only poor-to-moderate control. All other treatments were discontinued, except for one patient who used Diprolene cream on one elbow for comparison, and another patient who continued her usual twice weekly UVB treatments. The 10-30Kd Peat Preparation was applied topically twice daily to the involved sites. The results are shown in Table 1.

TABLE 1

Results of Treatments with Purified Peat Preparation

	WEEK OF TREATMENT														
	1			2			3			4			5		
	W	NC	I	W	NC	I	W	NC	I	W	NC	I	W	NC	I
SCALING	0	3	2	0	3	2	0	2	3	0	1	4	0	1	4*
ERYTHEMA	0	3	2	0	3	2	0	2	3	0	1	4	0	2	3
THICKNESS	0	3	2	0	3	2	0	2	3	0	2	3	0	2	3

W: Worse
NC: No change
I: Improved
*: Compete clearing in one patient

10-30Kd Peat Preparation was well tolerated without irritation or staining. Smaller, more recent and less thick plaques showed early improvement, i.e., within two weeks. The psoriasis plaques were less responsive when chronic and well established. The improvement in erythema and scale of the psoriasis plaques was seen in three of the five patients and improvement in scales was seen in four of the five patients. One patient had complete clearing of all his plaques except for a small residual area on the elbow. The 10-30Kd peat extract was equal in efficacy to a potent

steroid applied topically.

Pruritus/Cutaneous Pain - Patients 6-11

Patients 6-11 had non-urticarial conditions. This category is exclusive of those with pruritive eczema or Xeroxis. One patient had post scabetic pruritus. One had persistent scrotal idiopathic pruritus poorly controlled with topical steroids. Two had chronic pruritic nodularis. One had severe pruritus/cutaneous pain secondary to hepatic sarcoma. One had intense pruritus over the graft and keloidal area resulting from third degree burns over 40% of her body.

None of the patients except the post scabetic patient were controlled with oral H-1 and H-2 antagonists either alone or in combination (e.g., Seldane and Zantac or Doxepin alone). Application of the following topical agents did not produce satisfactory results: Prame Gel lotion, Zostrix, category 1 or 2 corticosteroid creams where appropriate, and non-fluorinated corticosteroids on the scrotum.

Upon application of a peat preparation comprising 3-30Kd peat preparation and peak #11, there was immediate relief of the pruritus. The pruritic nodularis patients reduced their excoriation to a minimal level. The post scabetic pruritus cleared over a week, but again relief was immediate. The previously unresponsive scrotal pruritus was completely relieved, but required two or three weeks of treatment to obtain resolution. The healed third degree burn patient had immediate relief and required six to eight applications a day to maintain relief. This intense application was not feasible on a continued basis and thus brief, quick but not lasting relief was obtained in this instance. The hepatic sarcoma patient was in her last two months of life and the continuous itch/pain was so severe that normal sleep and daily functioning was not possible.

In this case, she had not responded to the above-noted oral agents or Axsain cream. Application of the peat preparation produced an immediate improvement of both the itch and the deep burning pain sensation. She required four applications daily but no longer dug at her skin and was able to sleep.

Vesicular Hand/Foot Dermatitis - Patients 12-14

Human patients 12-14 were treated with a preparation comprising peak #11. In all cases, one pruritus was relieved immediately, but the vesicular-pustular component was not controlled. Two of the patients required systemic corticosteroids and either Ultravate or Temovate ointment for control. The third evolved into pustular psoriasis and is now using PUVA.

Atopic Dermatitis - Patients 15-20

Human patients 15-20 having chronic atopic dermatitis of the face were treated with 10-30 Kd Peat Preparation. All were experiencing intense pruritus of the dry facial eczema along with increasing lichenification resulting from the rubbing and inflammation. One also had similar severity in his hands/arms along with excoriation. In addition to the emollients, all were using either Locoid or Elocon cream twice daily on the facial eczema without control. All were showing signs of steroid atrophy.

The pruritus relief was immediate and the dermatitis cleared over 4-5 days. Remission of several weeks was observed in two patients and three were eventually maintained with once daily application. One patient completely cleared of active dermatitis and continued treatment for several months. After a three-week hiatus, treatment was resumed, but without the same response. This patient could not fully control the condition solely using a composition comprising peak #11. Twice weekly Locoid cream was required along with daily administration of peat extract

to control the pruritic dermatitis.

Dental Application - Patient 21

Patient 21 had four wisdom teeth extracted. Two of the teeth were seriously impacted. The patient was given a prescription for hydrocodone (a narcotic analgesic) and released. The patient was in a great deal of pain and, instead of taking the hydrocodone, he swished a few milliliters of a solution comprising peak #11 around in his mouth. The pain was relieved instantaneously. The patient repeated the administration at 30-minute intervals for about two hours. Administration at 2-hour intervals seemed to be sufficient thereafter. This patient continued with this schedule for approximately two days and was essentially pain free.

Burn - Patient 22

Patient 22 sustained second and third degree burns over most of three fingers on her right hand. The burns were caused by contact with a flame and by burning nylon that stuck to her fingers. The Emergency Room doctor diagnosed the burns, cut away the burned nylon and skin, and applied sulfadiazine. The sulfadiazine was later removed and a 3-30Kd peat preparation was applied. The patient dressed the wound at least twice daily with bandages soaked with the 3-30Kd peat preparation. The pain abated almost immediately upon application of the preparation and the wounds remained largely pain-free. Within 3 weeks, the patient's fingers were healed, but still pink. After 2 more weeks, there were no indications of scars or wound marks of any sort; the skin of the fingers appeared healthy in all respects.

Pain and Lesions - Patient 23

Patient 23 had a laminectomy and subsequently experienced spasms in his lower back. After eight months,

the patient was treated with a 10-30Kd Peat Preparation in a cream carrier and he was immediately relieved of pain. Patient 23 also has a long-lasting problem with his feet, which was reported to be jungle rot and which caused unbearable itching and open lesions. After applying the 10-30Kd Purified Peat Preparation cream to his feet, the pain and itching subsided and the odor disappeared.

Chronic Arthritis - Patient 24

Patient 24 had suffered from chronic arthritis for about twelve years and consulted several doctors and chiropractors over these years. Patient 24 was treated with various oral drugs and injections of cortisone, but none of these treatments provided relief. Patient 24 applied a 3-30Kd Peat Preparation topically to an inflamed foot, knee and shoulder twice daily. Within 5 days, there was significant relief in all areas. Patient 24 was able to discontinue use after about 10 days.

Eczema - Patients 25-29

Patient 25 had eczema for approximately 8 years. He had been unresponsive to other anti-eczema therapy and the eczema had never completely disappeared nor been effectively treated. He applied a solution comprising 10-30Kd Peat Preparation (2mg/ml) diluted with 15 ml water and 15 ml of a 0.004% solution of calcium gluconate (final pH 7.3) to well-established spots of eczema. Skin irritation (burning), thought to be caused by the calcium gluconate, occurred for approximately 30 minutes. Applications were continued twice daily for about 10 days. The affected area became quite red; however, all lesions disappeared within 8 days. The redness disappeared after treatment with Lidex cream for 2 days, leaving only slight discoloration of the skin. No lesions have reappeared in the same locations, but the eczema continued to present itself in different locations. The new

eczema spots were treated with a peat preparation that contained no calcium gluconate. These treatments produced positive results.

Patient 26 applied a 10-30Kd Peat Preparation to eczema covering both legs between his ankles and knees. Itching was so severe when the patient was in contact with warm or hot water that taking a shower was almost unbearable. Administering the preparation before a shower greatly reduced itching; used after, the itching stopped within 2 minutes.

Patient 27 had very difficult eczema over one-third of her body. She treated one arm with a 3-30Kd peat preparation and used the other arm as a control. The treated arm became clear, while the control arm had 25% coverage of eczema. Patient 27 also administered the preparation on her face and it eliminated the pain associated with the eczema on her face less than 15 seconds after application. Steroids were less effective.

Patient 28 had mild eczema which could be controlled with steroids using lengthy treatments. Upon application of a 3-30Kd peat preparation, he was free from lesions after 7 days.

Patient 29 had a large amount of eczema on her face. After applying a 10-30Kd Peat Preparation twice daily for one week, her face was cleared of all eczema. She continued treatment once daily for another three weeks. The eczema had still not re-emerged after two months.

Wound Healing - Patients 30 and 31

Patient 30 applied a 10-30Kd Peat Preparation to sores from abrasions. One of these sores was infected to the point that it was oozing and weeping. Within 2 to 3 days after treatment with the preparation was initiated, the redness and infection was completely gone and complete healing occurred. This healing occurred as soon, if not sooner, than another untreated sore which did not have any

apparent infection.

Patient 31 had open and bleeding sores on his hands caused by involuntary scratching of eczema during the night. Cortisone injections controlled the itching for about 4-6 weeks, but the patient was only able to take cortisone shots twice a year. After 2 days of treatment with a 10-30Kd Peat Preparation, the itching stopped and healing began. After 7 days, the eczema was completely controlled. When application of the preparation was discontinued, the eczema returned but to a lesser degree. Following 6 days of renewed treatment, the eczema once again disappeared. Patient 31 continued treatment with the preparation for 8 months with effective control of his eczema. No side effects were observed.

Psoriasis - Patients 32 and 33

Patient 32 had suffered from psoriasis on his arms and elbows for over ten years. A 10-30Kd Peat Preparation was applied to one elbow on a twice daily basis for approximately 9 months, with the occasional simultaneous application of fluocinonide cream. Fluocinonide cream alone was used on the other elbow.

The elbow treated with the fluocinonide alone evidenced only subsided flaking of the skin, but no decrease in the skin lesions. The patient observed significant improvement within one week by using the preparation combined with the occasional application of fluocinonide cream. Flaking and itching had stopped and the lesions on his skin were reduced in size. Hair started growing in these areas. Patient 32 also applied the preparation to open wounds such as minor cuts and observed good healing effects without infection.

Patient 33 had psoriasis that seemed to only manifest itself after a strep throat. Her only successful treatment had been with chemotherapeutic agents. Application

of a 10-30Kd Peat Preparation cleared up the treated psoriatic area in 2 to 3 weeks.

Epidermal Conditions - Patients 34-44

During the winter months, Patient 34 had an extreme case of dry skin and red rash on the inside of her legs. The itching immediately ceased upon application of the 10-30Kd Peat Preparation. Within one week, the red rash was gone and the dry skin was completely normal.

Patient 35 applied a 10-30Kd Peat Preparation to treat sumac poisoning on his legs and arms. He had previously used 1% cortisone treatment to soothe the burning and itching and to clear up the blisters, which took a week to 10 days. The skin would also turn red and peel like a sunburn before the irritation would stop. After applying the preparation, he had immediate relief from the burning and itching. Within 24 hours the blisters were gone, and within 48 hours the redness was gone and the skin looked normal.

Patient 36 applied a 10-30Kd Peat Preparation to her lip at the first sign of a cold sore. The preparation stopped the lesion from appearing. There was no pain after the first application.

Patient 37 experienced mouth sores from overuse of ibuprofen. A 10-30Kd Peat Preparation was applied directly to the sores and cured the condition in 12 hours. The healing process generally took 3-5 days if untreated. Patient 37 also applied the preparation to numerous cuts and abrasions to effectively avoid infection and accelerate the healing process. Pain was generally controlled within five seconds after application.

Patient 38 had boil-like conditions as a result of a lingering staphylococcal infection. The condition generally resulted in an infection that required lancing. After application of a 10-30Kd Peat Preparation to the affected areas three or four times daily for five days, the

condition completely healed. Patient 38 also applied the preparation to skin blemishes with excellent healing results.

Patient 39 treated a third-degree kitchen stove burn with a 10-30Kd Peat Preparation 10 minutes after the burn was sustained. The associated pain diminished in 15 seconds.

Patient 40 applied a 10-30Kd Peat Preparation to her leg about 24 hours after it was burned. At the time she applied the preparation, the burn was quite painful and blistered. Immediately after treatment, the pain subsided. Within 24 hours, the blistering was gone and the burned skin was smooth.

Two hours after Patient 41 burned his finger, it was blistered and weeping. After applying a 10-30Kd Peat Preparation, he experienced immediate relief. The blistering was gone overnight. Patient 41 also applied the preparation to finger inflamed by a steel sliver and there was an immediate reduction in pain and pressure.

Patient 42 experienced itching in his right eye. After one day, his eye became red and inflamed. Flushing with eye wash did not provide relief. After several days, the eye was completely stuck closed, very swollen and red, and the patient was diagnosed with conjunctivitis. The patient applied a cotton pad soaked with a 10-30Kd Peat Preparation. On the following day, the patient had very little swelling and no pain in his eye, but the eye was still red. He again applied a cotton pad soaked with the preparation before going to bed. On the following day, his eye had no swelling, no pain in the eye and no itching. Two days later, the eye was completely healed.

Patient 43 applied a 10-30Kd Peat Preparation to portions of a badly skinned knee. Within two days, all of the soreness and redness was gone and a thin layer scab had formed. The untreated area was still sore to the touch. The scab that formed on the treated area was much thinner than

that of the untreated. There was no pus-like substance at any time on the treated area, but there was a continuing secretion of pus for five days on the untreated area. The subject reported that overall healing of the treated wound was at least twice as fast as usual.

Patient 44 had acne congolbata on his back, buttocks, and legs. This is a severe, painful condition of boils which must be frequently lanced. He was being treated with Prednisone at a dose of 27 mg a day. This treatment barely contained the boils. The patient was visiting the Emergency Room at the hospital as much as once a week for lancing. He began using 60 mgs/250 ml peat preparation #44 in a cream. He was able to reduce the dose of Prednisone to 5 mg a day, with continued reduction of the Prednisone dose thereafter. With continuing treatment, the boils stopped erupting and the pain was diminished.

Fungal Condition - Patient 45

Patient 45 suffered from a chronic athlete's foot infection. He had been told by physicians that his condition was incurable. After one application of a 10-30Kd Peat Preparation, his condition began to clear. After the second and third applications, there was no evidence of the fungal infection.

Shingles - Patient 46

Two children were diagnosed with shingles. A prescribed medication was used on them for three weeks with no relief. Peat preparation #44 was administered topically and provided immediate relief form the pain. In two days, the lesions were gone.

Example 6

Mixtures and Complexes

Inorganic composition mixtures and/or composed of

complexes of the present invention were also synthesized and administered to human patients. Inorganic mixtures were prepared using a combination of gypsum ($CaSO_4 \cdot 2H_2O$) and potassium sulfate (K_2SO_4). More specifically, a "Mixture" containing 0.6 mg of equimolar $CaSO_4 \cdot 2H_2O$ and K_2SO_4 in a carrier comprising 2ml of ethanamine-N-N-diethyl-trifluoroacetate (EDT) and glycerol in a 1:1 ratio was formulated.

Patients 47 and 48 applied the Mixture to small, 0.5 - 1.0cm^2 acid burns. The Mixture totally relieved pain within 3-7 minutes after a single application. Treatment with a water placebo on some sites yielded no pain relief. Treatment with a 3-30Kd peat preparation yielded temporary pain relief after about 4 minutes, but additional treatments were required to sustain pain relief.

Patient 49 applied the Mixture topically to treat long-term low back pain due to nerve damage caused by disc deterioration. Pain relief occurred within seconds and was sustained.

Example 7

Synthesis of Syngenite

Syngenite was synthesized according to the following protocol. Solution A was formulated by dissolving 125 mmoles of K_2SO_4 in distilled water (450 ml) at room temperature. Solution B was formulated by mixing 2.5 mmoles $CaSO_4$ in distilled water (50 ml) at room temperature with constant stirring. Solution A was slowly poured into solution B with constant stirring. The reaction mixture was maintained for 4 hr at an isotherm of 38°C.

Upon evaporation of water, crystals formed which were filtered through a membrane filter. Crystals were washed with small amount of ice-cold water:methanol (1:1) then with ice-cold water and dried. The crystals thus obtained were recrystallized with water, resulting in the

formation of pure (>90%) syngenite.

Example 8

Comparative Studies

Experiments were conducted to compare the effectiveness of samples #44 and #46 to peak #11. Based upon the reports of the test subject, samples #44 and #46 both worked about 30% as well as peak #11. When samples #44 and #46 were administered in an EDT carrier, however, each sample produced results that were comparable to those obtained with peak #11.

Another patient topically administered three different preparations to an area of pain. The three preparations included: (1) a 3-30Kd peat preparation; (2) a peak #11 preparation in a cream; and (3) an equimolar mixture of $CaSO_4 \cdot 2H_2O$ and K_2SO_4 (each about 0.03% by weight) in 1,2,3-trihydroxypropanol. The preparations were applied to different areas to reduce intense pain associated with a chronic arthritic condition of many years' duration.

The patient reported that the 3-30Kd peat preparation produced noticeable but short-lived relief for 20 minutes, with some relief lasting for approximately one hour. He also reported that the peak #11 preparation provided substantial relief for 20 minutes after application, coupled with reduced relief for 3 to 4 hours. The patient furthermore reported that the use of the mixture in the 1,2,3-trihydroxypropanol carrier produced relief equivalent to the peak #11, and had the additional advantage that it was neither greasy nor sticky.

Example 9

Additional Comparative Studies

Three human subjects, two suffering low back pain and one with pain due to peripheral neuritis of the lower extremities, were each given four blinded samples for uniform

dose topical application. They were instructed to first apply sample #1 and then five minutes later to record the level of pain relief according to the following scale: No Relief=0%, Minor Relief=33%, Significant Relief=66%, and Complete Relief=100%. If No Relief or Minor Relief were noted, subjects were instructed to apply sample #2 to a new topical area of pain. The same general scheme was continued until all four samples had been tested. The results of the test were as follows:

Subjects' Responses

Sample No.	Complete	Significant	Minor	No Relief	Duration
#1	3/3				1-4+ hrs
#2		1/3	2/3		3 hours
#3			1/3	2/3	
#4				3/3	

The small size of this group permits only one clear conclusion. Sample #1 provides clear analgesic benefit for all subjects compared to the other samples. The composition of sample #1 was 0.25% $CaSO_4 \cdot 2H_2O$ plus 0.5% syngenite in UNIBASE cream. UNIBASE is a commercially available topical cream. The composition of samples #2, #3, and #4, respectively, was as follows: #2 = UNIBASE alone, #3 = 0.25% syngenite in UNIBASE and #4= .25% $CaSO_4 \cdot K_2SO_4 \cdot H_2O$ in UNIBASE. In the subject with pain due to neuritis there was also a very significant level of local inflammation which was virtually completely ameliorated by the application of sample #1.

This example demonstrates several important aspects of the invention. First, it utilized syngenite prepared by the claimed new synthetic process. Second, it showed that a formulation composed of calcium sulfate and another

sulfate-containing compound (syngenite) is responsible for the amelioration of pain and inflammation in human subjects. Third, since both of these compounds are known to be part of the 3-30Kd, 10-30Kd and #11, #44 and #46 fractions in variable proportions, we can conclude that at least some of the beneficial results produced by these preparations are due to the presence of these components.

Example 10

Veterinary Applications

The inorganic compositions of the present invention also demonstrate significant utility for veterinary applications. The results of several animal experiments are present below.

Animal subject A was a dog that started intensive scratching after a visit to the seashore. After two to five days, itching increased with some hair loss as a result of continued scratching. On day six, the dog was sprayed with flea and tick powder but showed no improvement. The bites continued to worsen and soon secreted a pus-like substance. The dog was treated by applying a 10-30Kd Peat Preparation in spray form. The spray was re-applied 8 hours later. On the following day, there was no pus and less scratching. The preparation was reapplied three times during the day and the bites were smaller and less red. After one more day of treatment, the bites were smaller in size, only pink in color and there was no scratching.

Animal subject B was a race horse suffering from sores on its legs. The horse was diagnosed as being allergic to mud and was treated with triamcinolone 0.1% acetonide cream. He had scabbing and oozing of pus on his legs and was sore and stiff. There was no improvement after four months of treatment under veterinary supervision. A 10-30Kd Peat Preparation was sprayed directly on the horse's legs once a day. After three days, healing was noted. After one week,

the infected areas were healed and the horse's hair was growing back.

Animal subject C was a large dog that had serious eczema and dry skin since birth. Numerous sprays, powders, shampoos, pills and injections were administered without success. After spraying the dog with a 10-30Kd Peat Preparation for two weeks, itching was resolved and there was less flaking and dry skin.

Animal subjects D and E were adult Labrador Retrievers infested with fleas. A 10-30Kd Peat Preparation was applied in a liquid form three to four times daily to the thighs, perianal region and tails of two dogs. No other attempt was made to treat the fleas on the dogs or in their environment. Prior to treatment, bitten fur and a flea-induced dermatitis was obvious. Immediate reduction in biting, scratching and licking of the involved sites was apparent upon initial application of the preparation. Since the flea population was not reduced, four daily treatments were required for control of the pruritus and clearance of the dermatitis.

Animal subject F, a German Short Hair dog, was treated with the 10-30Kd Peat Preparation for a non-flea associated, non-specific dermatitis. Applications were inconsistent and usually twice daily. There was a noticeable reduction in the scratching and dermatitis within one week.

An open clinical trial was conducted in an attempt to determine the efficacy of a 10-30Kd Peat Preparation when topically applied for treating a variety of itching canine skin diseases. Most of the dogs suffered from allergy-associated itch (flea bite, inhaled and/or food allergies). In over 50 dogs evaluated, the preparation was instrumental in the relief of itch in greater than 50% of the subjects. No adverse side effects were noted. Itch relief was usually noted within three days of initiating therapy. Additionally, the preparation demonstrated significant anti-inflammatory

properties (rapid decrease in erythema and swelling) when applied to allergy-associated rashes. Preparations comprising syngenite produced synthetically according to the protocol given in Example 7 produced similar therapeutic results when administered to dogs.

Example 11

Treatment of Bovine Squamous Cell Carcinoma

Bovine ocular squamous cell carcinoma of cattle is a common neoplasm of the bovine eye and adenexa. Squamous cell carcinomas may also affect other species of animals. Bovine ocular squamous cell carcinoma is best known by its colloquial name of Cancer-eye. The initial lesion may be on the eyelid or any structure in the conjunctival sac except the vascular cornea or the pigmented eyelid. The lesion develops through three stages. The first stage is the formation of a plaque; the second stage is formation of a papilloma; and the third stage is the squamous cell carcinoma.

The first two stages are non-malignant and have up to an 88% regression rate. The third stage is malignant and does not regress. These carcinomas develop most commonly on the nictating membrane, the eyelids, and the corneal limbus. They grow rapidly and are actively invasive, often metastasizing to the lymph nodes. The above-described cancer most usually affects Hereford cattle, but has been found in Ayrshire, Simmental, Shorthorn, Holstein and cross-bred animals thereof. Several cattle were successfully treated with a 10-30Kd Peat Preparation.

A cow having bovine ocular squamous cell carcinoma was treated by injecting 5 ml of a solution containing 3 mg/ml 10-30Kd Peat Preparation into the sarcoma. Ten days later the tissue firmed up, blood supply increased and the tumor had shrunk considerably. Three weeks later, there were no visible signs of the tumor remaining.

Another cow was treated using a slightly different treatment regimen. The original lesion measured 5 cm x 2½ cm. Initial treatment consisted of debriding the necrotic areas, and then suturing 4 gauze pads over the right eye after injecting 1 ml of a 10-30Kd Peat Preparation into the tumor. The gauze was subsequently soaked liberally with the preparation. The soaked gauze was covered and an eye patch was applied. This treatment procedure was repeated weekly for five weeks. During this time, the size of the tumor reduced substantially.

A 12-year old purebred Hereford cow had a squamous cell carcinoma on its upper and lower left eyelids and nictating membrane. Necrotic tissue was debrided under local anesthesia, a biopsy sample was taken, and 3 ml of the 10-30Kd Peat Preparation was injection into the lesion. The examination and treatment were repeated after 9 days and considerable improvement was noted. The treatment was repeated after 49 days. A second growth was found on the right eye, which was also treated. After two months, the cow appeared to be healthy and tumor-free.

Another cow had a squamous cell carcinoma lesion .5 cm^2 on its corneal limbus. The growth was surgically removed, and then 0.5 ml of 10-30Kd Peat Preparation was injected into area. No further treatment was administered for one year, when a small plaque was removed.

The examples presented above are to be considered in all respects as illustrative and not restrictive. The scope of the invention is indicated by the appended claims only, and all modifications which come within the meaning and equivalency of the claims therefore are intended to be embraced therein.

WE CLAIM:

1. A pharmaceutically acceptable composition comprising a complex of a calcium-containing component and a sulfate-containing component in a pharmaceutically acceptable carrier or diluent.

2. A pharmaceutically acceptable composition according to claim 1, wherein the complex is calcium sulfate.

3. A pharmaceutically acceptable composition according to claim 1, comprising a complex of a calcium-containing component and potassium sulfate.

4. A pharmaceutically acceptable composition according to claim 3, wherein the calcium-containing component is calcium sulfate.

5. A pharmaceutically acceptable composition according to claim 4, wherein the complex of calcium sulfate and potassium sulfate is syngenite.

6. A pharmaceutically acceptable composition according to claim 1, comprising a calcium-containing component in addition to the complex.

7. A pharmaceutically acceptable composition according to claim 1, additionally comprising a complex of potassium-sodium-sulfate.

8. A pharmaceutically acceptable composition according to claim 7, wherein the complex of potassium-sodium-sulfate is apthitalite ($K_3Na(SO_4)_2$).

9. A pharmaceutically acceptable composition according to claim 1, comprising one or more of the following components: $MgSO_4$; K_2SO_4; $Al_2(SO_4)_3$; $CaSO_4$; $CaSO_4 \cdot 1/2H_2O$; $CaSO_4 \cdot 2H_2O$; $2CaSO_4 \cdot MgSO_4 \cdot K_2SO_4 \cdot 2H_2O$; $3CaO \cdot Al_2O_3 \cdot 3CaSO_4 \cdot 32H_2O$; $CaSO_4 \cdot Na_2SO_4$; $Na_2SO_4 \cdot 10H_2O$; $K_2SO_4 \cdot 5CaSO_4$; $NaAlSi_3O_8$; and $KAlSi_3O_8$.

10. A pharmaceutically acceptable composition according to claim 1, additionally comprising one or more of the following constituents: sodium; magnesium; silicon;

chlorine; potassium; strontium; zinc; copper; aluminum; nickel; and manganese.

11. A pharmaceutically acceptable composition according to claim 1, wherein the carrier or diluent is aqueous.

12. A pharmaceutically acceptable composition according to claim 1, wherein the carrier or diluent comprises 1,2,3-trihydroxypropanol.

13. A pharmaceutically acceptable composition according to claim 1, wherein the carrier or diluent is a topical cream.

14. A pharmaceutically acceptable composition according to claim 1, wherein the complex is derived from peat.

15. A pharmaceutically acceptable composition according to claim 14, wherein the complex is derived from a .5-30 Kd peat fraction.

16. A pharmaceutically acceptable composition according to claim 14, wherein the complex is derived from a 10-30 Kd peat fraction.

17. A pharmaceutically acceptable composition comprising a mixture of a calcium-containing component and a sulfate-containing component in a pharmaceutically acceptable carrier or diluent.

18. A pharmaceutically acceptable preparation according to claim 17, wherein the calcium-containing composition is calcium sulfate.

19. A pharmaceutically acceptable composition according to claim 17, comprising a mixture of a calcium-containing component and potassium sulfate.

20. A pharmaceutically acceptable composition according to claim 17, wherein the calcium-containing component is calcium sulfate.

21. A pharmaceutically acceptable composition according to claim 17, wherein the sulfate-containing

component is syngenite.

22. A pharmaceutically acceptable composition according to claim 17, comprising a complex of a calcium-containing component and a sulfate-containing component in addition to the mixture.

23. A pharmaceutically acceptable composition according to claim 17, additionally comprising a complex of potassium-sodium-sulfate.

24. A pharmaceutically acceptable composition according to claim 23, wherein the complex of potassium-sodium-sulfate is apthitalite ($K_3Na(SO_4)_2$).

25. A pharmaceutically acceptable composition according to claim 17, comprising one or more of the following components: $MgSO_4$; K_2SO_4; $Al_2(SO_4)_3$; $CaSO_4$; $CaSO_4 \cdot 1/2H_2O$; $CaSO_4 \cdot 2H_2O$; $2CaSO_4 \cdot MgSO_4 \cdot K_2SO_4 \cdot 2H_2O$; $3CaO \cdot Al_2O_3 \cdot 3CaSO_4 \cdot 32H_2O$; $CaSO_4 \cdot Na_2SO_4$; $Na_2SO_4 \cdot 10H_2O$; $K_2SO_4 \cdot 5CaSO_4$; $NaAlSi_3O_8$; and $KAlSi_3O_8$.

26. A pharmaceutically acceptable composition according to claim 17, additionally comprising one or more of the following constituents: sodium; magnesium; silicon; chlorine; potassium; strontium; zinc; copper; aluminum; nickel; and manganese.

27. A pharmaceutically acceptable composition according to claim 17, wherein the carrier or diluent is aqueous.

28. A pharmaceutically acceptable composition according to claim 17, wherein the carrier or diluent comprises 1,2,3-trihydroxypropanol.

29. A pharmaceutically acceptable composition according to claim 17, wherein the carrier or diluent is a topical cream.

30. A pharmaceutically acceptable composition according to claim 17, wherein at least one of the components is derived from peat.

31. A pharmaceutically acceptable composition

according to claim 30, wherein at least one of the components is derived from a .5-30 Kd peat fraction.

32. A pharmaceutically acceptable composition according to claim 30, wherein at least one of the components is derived from a 10-30 Kd peat fraction.

33. A method for synthesizing a complex of calcium sulfate and potassium sulfate comprising: mixing an aqueous solution of calcium sulfate with an aqueous solution and molar excess of potassium sulfate.

34. A method for synthesizing a complex according to claim 33, wherein a molar excess of potassium sulfate of about 3-fold to about 10-fold is provided in the reaction mixture.

35. A complex of calcium sulfate and potassium sulfate produced according to the method of claim 33 in a pharmaceutically acceptable carrier or diluent.

36. A pharmaceutically acceptable composition comprising a complex of calcium sulfate and potassium sulfate produced according to the method of claim 36.

37. A method for reducing inflammation in warm-blooded animals by administering the pharmaceutically acceptable composition of one of claims 1, 17 or 36.

38. A method for reducing pain in warm-blooded animals by administering the pharmaceutically acceptable composition of one of claims 1, 17 or 36.

39. A method for reducing itch in warm-blooded animals by administering the pharmaceutically acceptable composition of one of claims 1, 17 or 36.

40. A method for reducing abnormal proliferative cell growth in warm-blooded animals by administering the pharmaceutically acceptable composition of one of claims 1, 17 or 36.

41. A method for promoting wound healing in warm-blooded animals by administering the pharmaceutically acceptable composition of one of claims 1, 17 and 36.

42. A method for treating fungal infections in warm-blooded animals by administering the pharmaceutically acceptable composition of one of claims 1, 17 or 36.

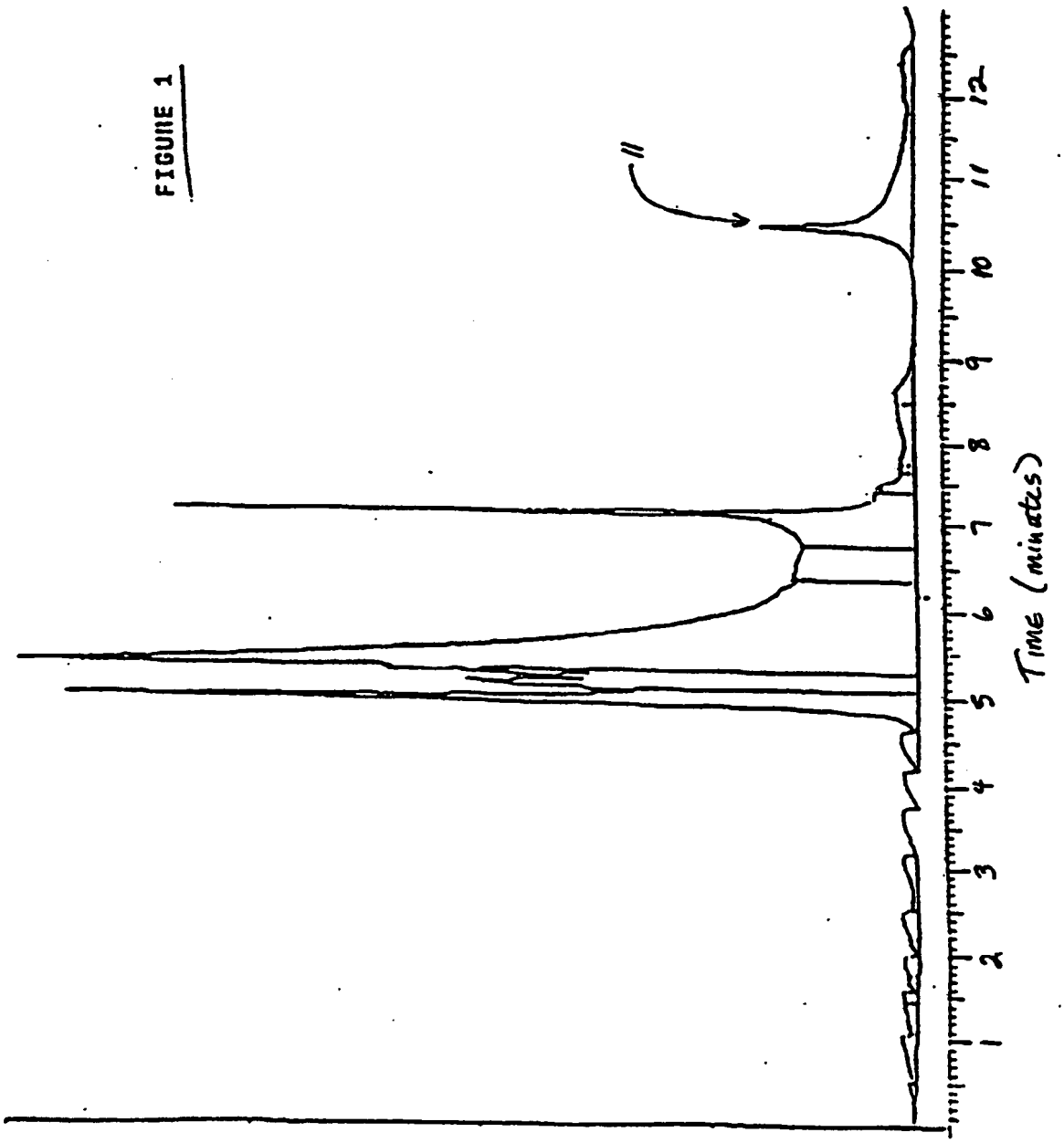
43. A method for treating bacterial infections in warm-blooded animals by administering the pharmaceutically acceptable composition of one of claims 1, 17 or 36.

44. A method for treating viral infections in warm-blooded animals by administering the pharmaceutically acceptable composition of one of claims 1, 17 or 36.

45. A cosmetic preparation comprising a complex of a calcium-containing component and a sulfate-containing component.

46. A cosmetic preparation comprising a mixture of a calcium-containing component and a sulfate-containing component.

FIGURE 1



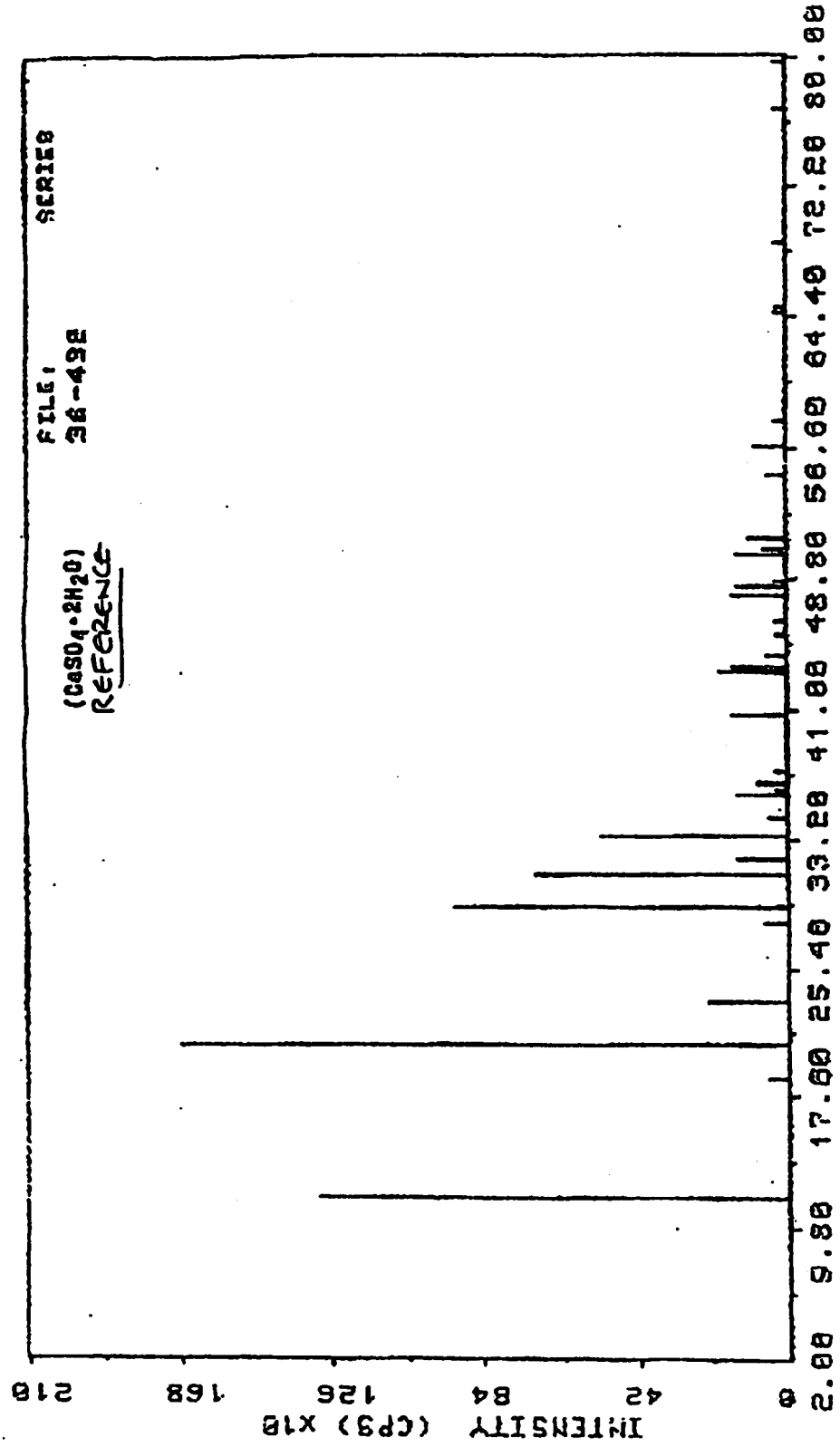

SERIES
FILE: 36-432
(CaSO4·2H2O)
REFERENCE
INTENSITY (CPS) X10
0
42
84
126
168
210
2.00
9.80
17.60
25.40
33.20
41.00
48.80
56.60
64.40
72.20
80.00
TWO - THETA (DEGREES)

FIGURE 2.

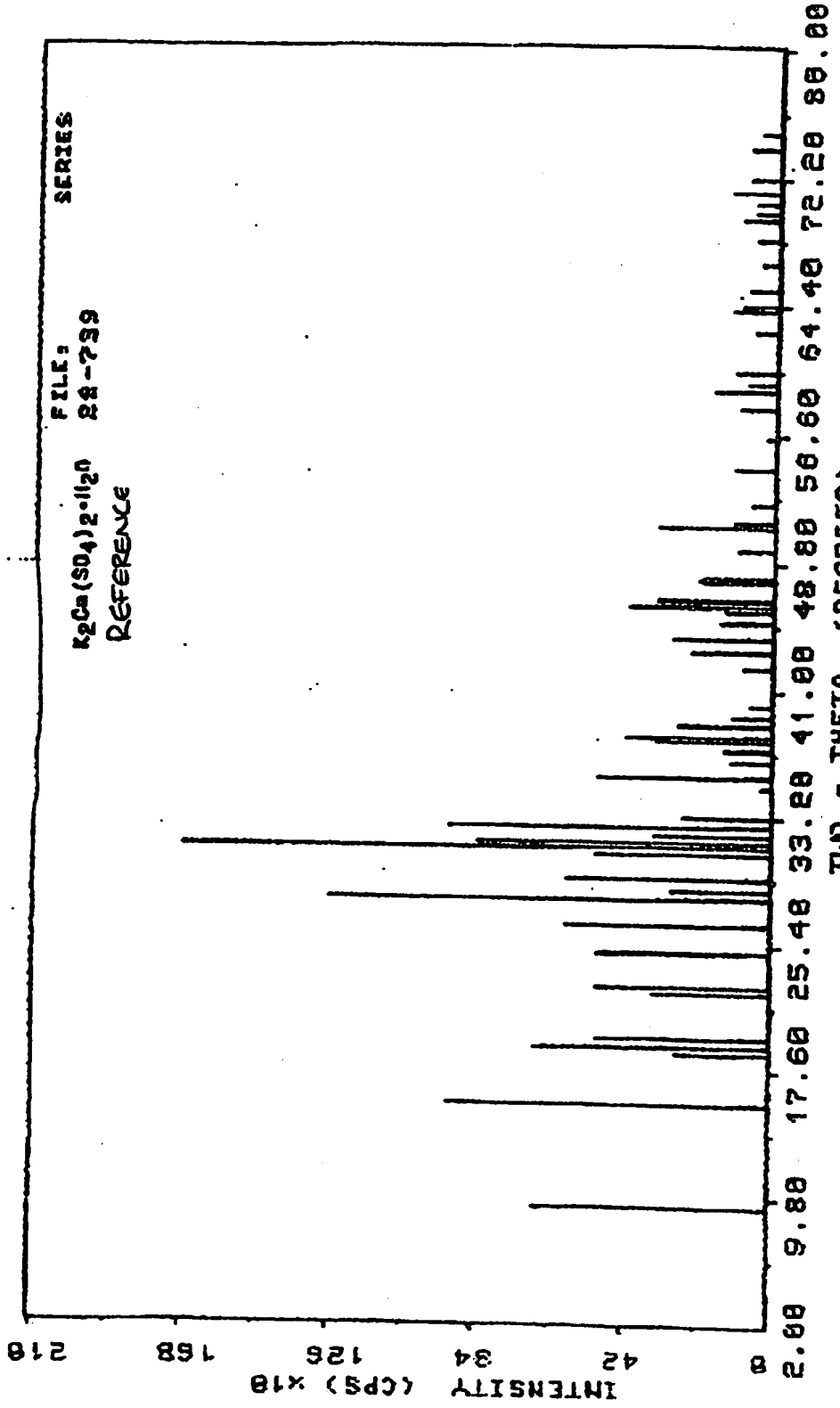

SERIES
FILE: 28-739
$K_2Ca(SO_4)_2 \cdot H_2O$
REFERENCE
2.00 9.80 17.60 25.40 33.20 41.00 48.80 56.60 64.40 72.20 80.00
TWO - THETA (DEGREES)
0 42 84 126 168 210
INTENSITY (CPS) x10

FIGURE 3.

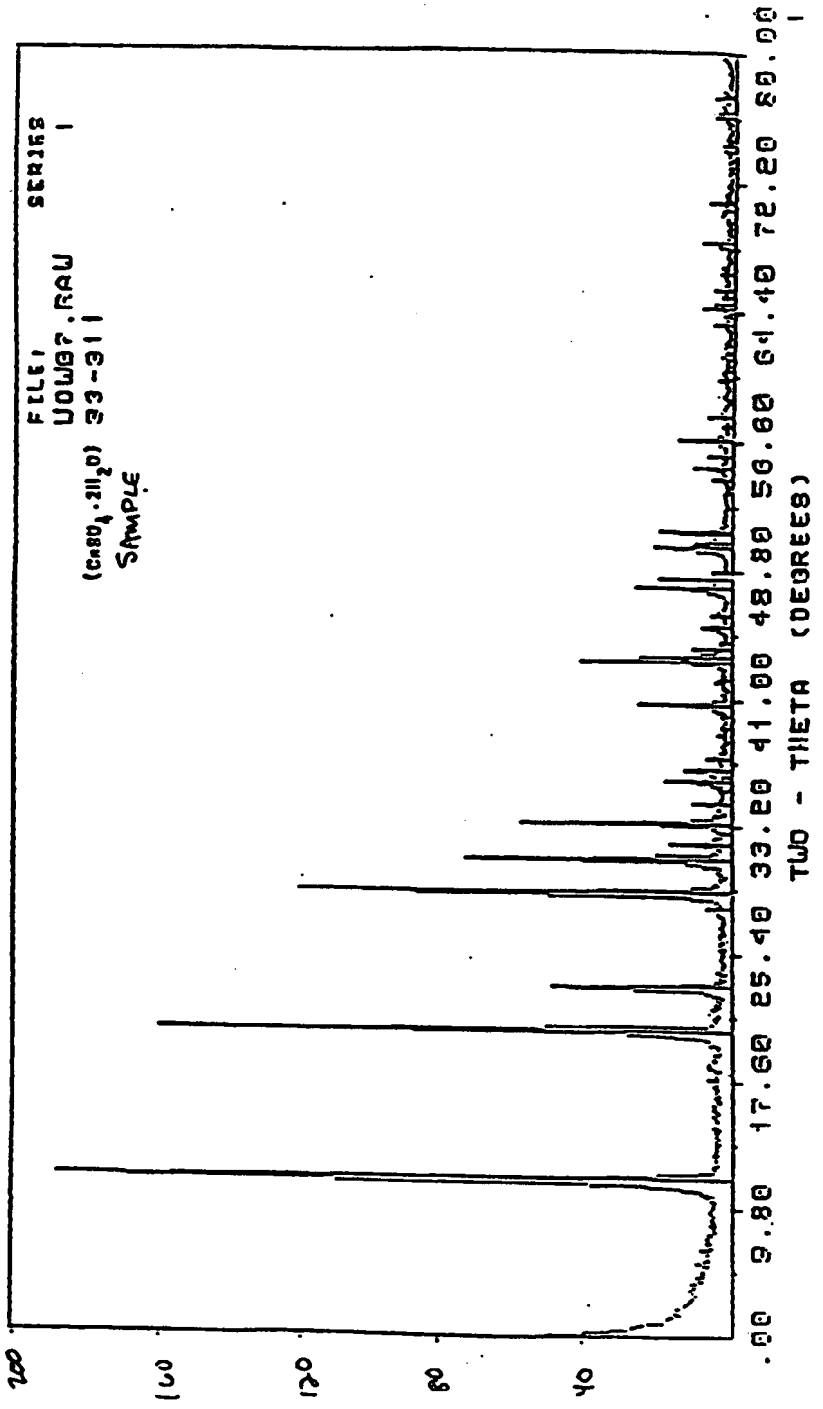

FILE: U0W87.RAW SERIES 1
(CaSO4.2H2O) 93-311
SAMPLE
.00 9.80 17.60 25.40 33.20 41.00 48.80 56.60 64.40 72.20 80.00
TWO - THETA (DEGREES)
140
120
80
40

FIGURE 4.

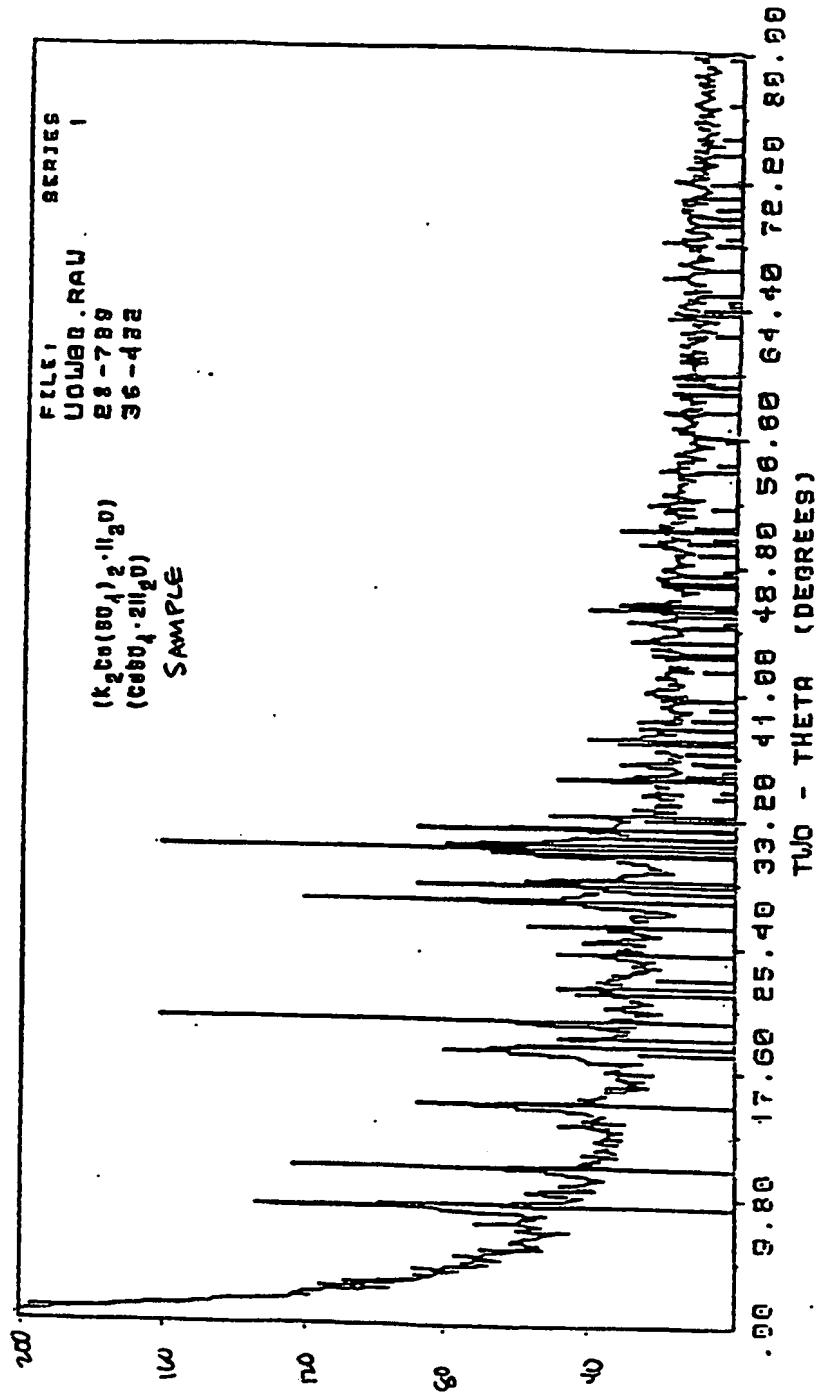

FILE: UOW80.RAW
SERIES 1
28-789
36-432
$(K_2Ca(SO_4)_2 \cdot H_2O)$
$(CaSO_4 \cdot 2H_2O)$
SAMPLE
100
80
60
40
.00 9.80 17.60 25.40 33.20 41.00 48.80 56.60 64.40 72.20 80.00
TWO - THETA (DEGREES)

FIGURE 5

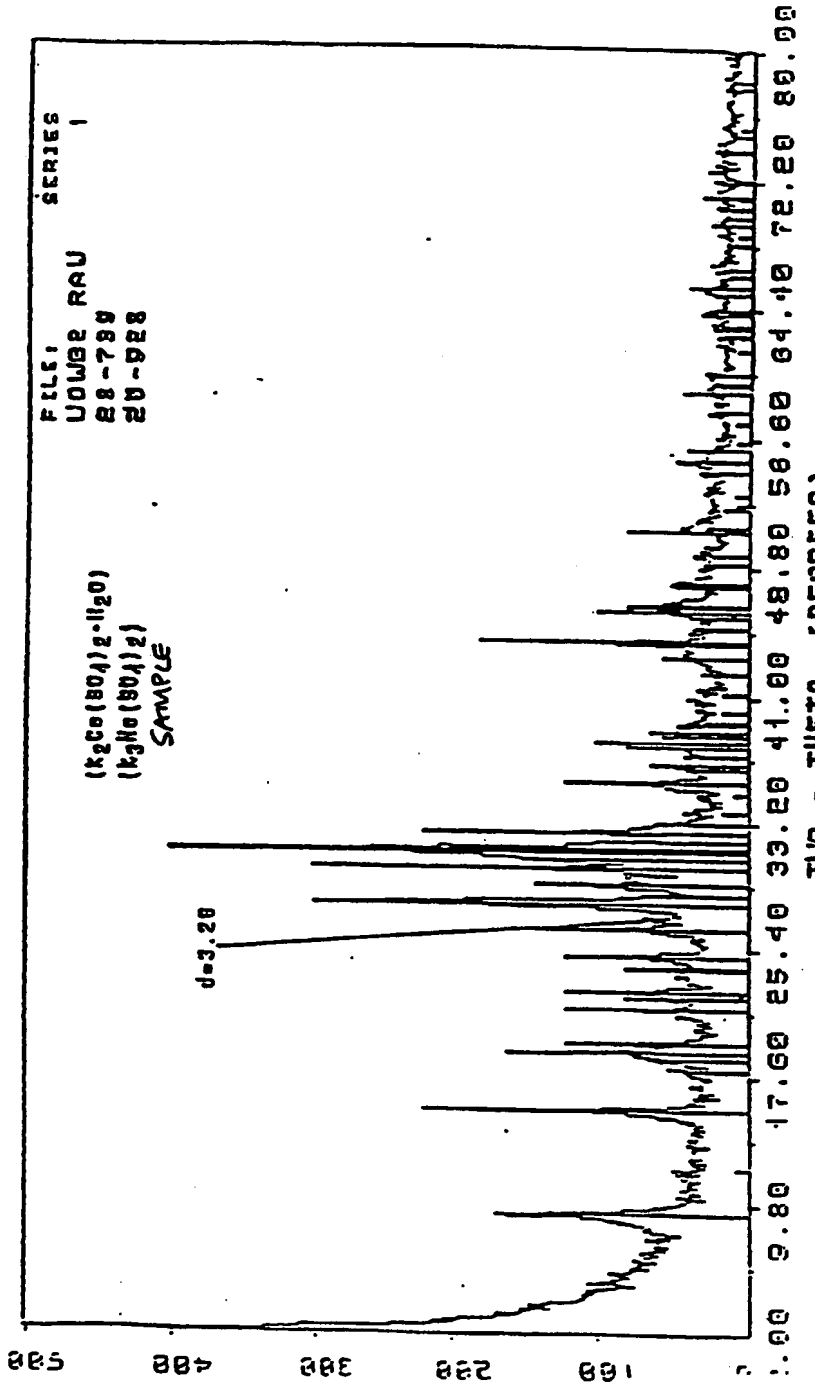

FILE: UOW02 RAU
SERIES 1
88-739
20-928
(K2Co(SO4)2·H2O)
(K3Na(SO4)2)
SAMPLE
d=3.28
TWO - THETA (DEGREES)
0.00
9.80
17.60
25.40
33.20
41.00
48.80
56.60
64.40
72.20
80.00
168
288
408
528

FIGURE 6

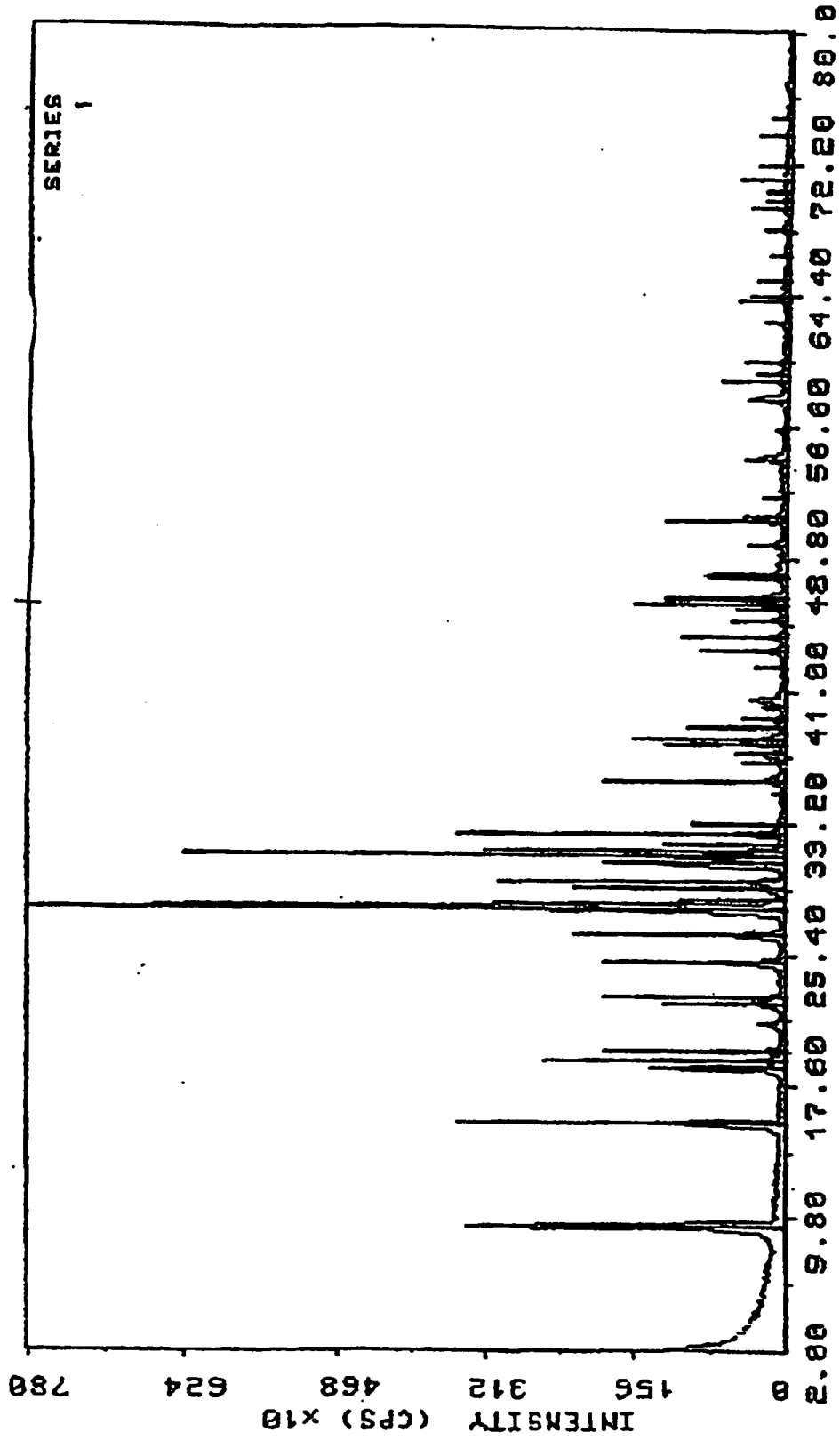

SERIES 1
INTENSITY (CPS) x10
0
156
312
468
624
780
2.00
9.80
17.60
25.40
33.20
41.00
48.80
56.60
64.40
72.20
80.0
TWO - THETA (DEGREES)

FIGURE 7